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- with international search report
- with amended claims

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Date of publication of the amended claims: 24 June 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2004/014156 A3

(54) Title: A CHEMICAL CARRIER BASED ON A BETA-LIMIT DEXTRIN

(57) Abstract: A formulation, especially a pharmaceutical formulation, comprises an active agent and a carrier for the active agent, wherein the carrier comprises a  $\beta$ -limit dextrin. The formulation may be a bioadhesive pharmaceutical formulation in which the  $\beta$ -limit dextrin acts as a mucoadhesive agent. The active agent is a pharmaceutically active agent or a flavour or fragrance which is intended for delivery into the buccal cavity. A use of  $\beta$ -limit dextrin as a disintegrant, a dispersant, and a mucoadhesive agent is also described. Also described is a nutritional product such as an energy drink which includes  $\beta$ -limit dextrin as an energy source.

## AMENDED CLAIMS

1 [received by the International Bureau on 12 March 2004 (12.03.04);  
2 original claims 1 to 31 replaced by amended claims 1 to 25;]

3

4 1. A bioadhesive pharmaceutical formulation  
5 comprising an active agent and a mucoadhesive  
6 carrier for the active agent, wherein the  
7 mucoadhesive carrier comprises a  $\beta$ -limit dextrin.

8

9 2. A bioadhesive pharmaceutical formulation as  
10 claimed in Claim 1 in which the  $\beta$ -limit dextrin is  
11 obtainable by hydrolysing starch with  $\beta$ -amylase.

12

13 3. A bioadhesive pharmaceutical formulation as  
14 claimed in Claims 1 or 2 in which the active agent  
15 is a pharmaceutically active agent.

16

17 4. A bioadhesive pharmaceutical formulation as  
18 claimed in any preceding claim which is a buccal-  
19 melt type product.

20

21 5. A bioadhesive pharmaceutical formulation as  
22 claimed in Claim 4 which is a wafer.

23

24 6. A bioadhesive pharmaceutical formulation as  
25 claimed in any of Claims 1 to 3 which is a powder  
26 for use in aerosol delivery formulations.

27

28 7. A bioadhesive pharmaceutical formulation as  
29 claimed in any of Claims 1 to 3 which is a thin  
30 film.

31

1 8. A bioadhesive pharmaceutical formulation as  
2 claimed in any preceding claims further including at  
3 least one carbohydrate.

4

5 9. A bioadhesive pharmaceutical formulation as  
6 claimed in Claim 8 in which the at least one  
7 carbohydrate is a polysaccharide.

8

9 10. A bioadhesive pharmaceutical formulation as  
10 claimed in Claim 8 in which the at least one  
11 carbohydrate is selected from the group comprising:  
12 alginate; pectin; and derivatives of alginate and  
13 pectin.

14

15 11. A bioadhesive pharmaceutical formulation as  
16 claimed in Claim 10 in which the alginate comprises  
17 between 1 and 50% of the formulation (w/w).

18

19 12. A bioadhesive pharmaceutical formulation as  
20 claimed in Claim 11 in which the alginate comprises  
21 between 10 and 30% of the formulation (w/w).

22

23 13. Use of  $\beta$ -limit dextrin as a mucoadhesive  
24 carrier.

25

26 14. Use of  $\beta$ -limit dextrin as a mucoadhesive  
27 carrier in a pharmaceutical formulation.

28

29 15. Use of  $\beta$ -limit dextrin as a mucoadhesive  
30 carrier in a thin-film breath freshener.

31

1 16. A bioadhesive pharmaceutical formulation as  
2 claimed in any of Claims 1 to 12 in a form selected  
3 from the group comprising: particulate; capsule;  
4 tablet; freeze dried matrix; wafer; liquid; and thin  
5 film.

6

7 17. A nutritional product comprising  $\beta$ -limit  
8 dextrin in which the  $\beta$ -limit dextrin is a main  
9 energy source in the product.

10

11 18. A nutritional product as claimed in Claim 17  
12 which is an energy drink.

13

14 19. A nutritional product as claimed in Claim 17 or  
15 18 which is a confectionery product.

16

17 20. Use of  $\beta$ -limit dextrin as an energy source in a  
18 nutritional product.

19

20 21. Use of  $\beta$ -limit dextrin as a slow release energy  
21 source in a nutritional product.

22

23 22. Use as claimed in Claim 20 or 21 in which the  
24 nutritional product is an energy drink.

25

26 23. A formulation, or use, as claimed in any  
27 preceding Claim in which the  $\beta$ -limit dextrin is  
28 obtainable by hydrolysing starch.

29

1 24. A formulation, or use, as claimed in Claim 23  
2 in which the  $\beta$ -limit dextrin is obtainable by  
3 hydrolysing starch with  $\beta$ -amylase.

4

5 25. A formulation, or use as claimed in Claim 23 or  
6 24 in which the starch is a waxy starch.

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/EP 03/08358A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A23L1/09 C12P19/22 A61K47/36

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A23L A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, FSTA

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category <sup>a</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 482 560 A (AMMERAAL ROBERT ET AL) 9 January 1996 (1996-01-09) column 1, line 28-52; claims 11-13; example 1 ---	22-31
X	US 4 780 149 A (REINDERS MEINDERT A ET AL) 25 October 1988 (1988-10-25) column 2, line 57 -column 3, line 42; claim 1; examples 1,2 ---	1-31

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

## ° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the International filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the International filing date but later than the priority date claimed

"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

5 February 2004

13/02/2004

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EP 03/08358

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
  
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-31

claims 1-21 cover pharmaceutical formulations with beta limit dextrins whereas claims 22-31 cover food products with beta limit dextrins  
both products, pharmaceuticals and food are already known comprising beta limit dextrins  
delimitation will lead to non-unitarian subject matter (a posteriori non-unity)  
the source of the beta limit dextrin can not serve to delimit (waxy starch treated with beta amylase is already disclosed in both cited documents)  
in the two partial inventions the beta limit amylase is used either as improving the bioadhesion (in the pharmaceutical product) or as energy source (in the food product)

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/EP 03/08358

Patent document cited in search report	Publication date		Patent family member(s)		Publication date
US 5482560	A 09-01-1996	AU BE FR GB	2334295 A 1008583 A3 2723106 A1 2291882 A		08-02-1996 04-06-1996 02-02-1996 07-02-1996
US 4780149	A 25-10-1988	NL EP	8600937 A 0242913 A2		02-11-1987 28-10-1987